IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE:	
BRIMONIDINE PATENT LITIGATION	C.A. No. 07-md-01866 GMS

ALLERGAN INC.'S BRIEF IN RESPONSE TO EXELA'S OPENING MARKMAN BRIEF

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Dated: June 16, 2008

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I. INTRODUCTION

Two terms are in dispute in this case: "about" and "therapeutically effective," both from the '834 patent, the only patent in dispute between Allergan and the Exela defendants. For these terms and all others, Apotex and Allergan agree that the plain and ordinary meaning should control and have agreed on proposed constructions that, in most cases, mirror the language of the claims. [*See* D.I. 46] Consistent with this Court's prior ruling, Allergan and Apotex also agree that the appropriate construction for "about" is "approximately." And Allergan and Apotex agree that the appropriate construction for "therapeutically effective" is just that — "therapeutically effective."

While giving lip service to the "plain and ordinary meaning," the Exela defendants' proposed constructions for "about" and "therapeutically effective" are far from that — in each case, the Exela defendants rewrite simple claim language into complex, lengthy expositions. The Exela defendants' initial proposal to construe "about" essentially asks the Court to read the term out of the claim entirely, while their fallback position argues disclaimer where there is none. And despite the fact that courts have held that the claim term "therapeutically effective" is a straightforward and comprehensible term, requiring no construction even in a jury case, Exela's proposed construction adds additional language to the term to an unknown end in this bench trial case.

There is no basis in the intrinsic evidence for limiting the ordinary meaning of the claims. The Court should reject Exela's proposed constructions and apply the ordinary meaning of the contested claim terms as proposed by Allergan and Apotex.

II. ARGUMENT

A. The '834 Patent uses the term "about" in its ordinary sense, meaning "approximately"

1. The claims are presumptively entitled to the full scope of the ordinary meaning of "about," which is "approximately"

The term "about" appears throughout the claims of the '834 patent. By way of example, Claim 1 uses the term three times with reference to three different quantities: the concentration of the drug ("up to about 0.15%"), the pH of the solution ("about 7.0 or greater") and the temperature ("about 21° C"):

> 1. A therapeutically effective aqueous ophthalmic composition comprising:
>
> up to *about* 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate, the composition having a pH of *about* 7.0 or greater, and the 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate being soluble in the composition at *about* 21° C.

[Tab 5 at A0054, '834 patent, col. 16:45-51 (emphasis added).]

It is hornbook caselaw that claims are presumptively entitled to carry the full scope of their ordinary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). The ordinary meaning of the term "about" is "approximately." *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369-70 (Fed. Cir. 2005) (holding that the ordinary meaning of "about" is "approximately").

In line with this authority, this Court previously construed "about" to mean "approximately" universally in the claims over arguments that the term should be limited. [1] *Allergan, Inc. v. Alcon, Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (Markman Order). And while Allergan understands that the Court is not bound by its earlier construction, that

[1] The Exela defendants' "measurement tolerances" arguments are in essence the same as those raised by Alcon and rejected by the Court in the previous case. Alcon, like Exela, argued that "about" should be limited to "within measurement error," another phrasing for " within measurement tolerances." See Memorandum in Support of Alcon's Proposed Claim Construction, filed May 2, 2005 (C.A. No. 04-968-GMS) (D.I. 54). The Court properly rejected Alcon's proposed construction in favor of the plain and ordinary meaning and should do so again here.

construction is not only supported by the *Merck* case, but also is in line with authority holding that a term used multiple times in the same patent should be interpreted consistently in each use. *See, e.g., Callicrate v. Wadsworth Mfg., Inc*., 427 F.3d 1361, 1371 (Fed. Cir. 2005) ("Of course, this court interprets claim terms consistently throughout various claims of the same patent."); *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1031 (Fed. Cir. 2002) (stating "[a] word or phrase used consistently throughout a claim should be interpreted consistently.") (*quoting Phonometrics, Inc. v. N. Telecom Inc.*, 133 F.3d 1459, 1465 (Fed. Cir. 1998)).

Consistent with this authority and prior ruling, Allergan and Apotex have proposed that, in all its uses in the '834 patent claims, "about" be construed in accordance with its ordinary meaning of "approximately." The Exela defendants, on the other hand, agree with the ordinary meaning for two of the uses of "about," (i.e., concentration and temperature)[2] but, with respect to its use in the term "a pH of about 7.0 or greater," propose a two-fold definition, requesting that "a pH of about 7.0 or greater" be construed to mean "a pH of 7.0 or greater within measurement tolerances" and arguing that "[i]n no event can the claim cover a formulation having a pH of 6.8 or below." [D.I. 48, Exela Defs. Br. at 12.] Both parts of the Exela defendants' proposed construction impose artificial limitations found nowhere in the intrinsic evidence and should be rejected.

2. The Claim language does not support the Exela defendants' proposed construction that "about" should be limited to "within measurement tolerances"

The first and most important source of intrinsic evidence is, of course, the claims themselves. On this score, the Exela defendants' construction finds no support. Rather, the opposite is the case.

[2] The Exela defendants offer no explanation for the inconsistency other than to say that it should not be taken as an admission of anything. [D.I. 48, Exela Defs. Brief at 2, n. 3]

In essence, the Exela defendants would read the word "about" out of the claim and replace it with "within measurement tolerances." This phrase is found nowhere in the claims (or anywhere else in the patent) – something that could readily have been done had that been the intended meaning. Instead, the claims use the term "about" without any modifiers, strongly suggesting that the ordinary meaning should control.

Moreover, the claims that do *not* use the term "about" as it relates to pH demonstrate further why the Exela defendants are wrong. Unasserted (against the Exela defendants) claims 5 and 14 drop the word "about" from the phrase "greater than about 7.0" and simply state that the formulation has a "ph of 7.0 or greater," which is very similar to the Exela defendants' proposed construction minus the phrase "within measurement tolerances."

By dropping the word "about," claims 5 and 14 thus require a more precise measurement of pH than Claim 1. *See Free Motion Fitness, Inc. v. Cybex Int'l., Inc.*, 423 F.3d 1343, 1351 (Fed. Cir. 2005) ("The doctrine of claim differentiation 'create[s] a presumption that each claim in a patent has a different scope.'"). This further precision in dependent claims 5 and 14 strongly suggests that the independent claims should not be limited to "the measurement tolerances" of pH. Rather, were they in dispute, it would be the dependent claims that might suggest the requirement of some kind of "measurement tolerance."

In their brief, the Exela defendants point to nothing in the claims themselves that supports their position. Accordingly, the first and most important source of intrinsic evidence supports simply applying the ordinary meaning. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) ("[The] Supreme Court made clear that the claims are 'of primary importance, in the effort to ascertain precisely what it is that is patented.'"); *see Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998) ("[T]he claims define the scope of the right to

exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim.").

3. The Exela defendants' proposed construction for "about" is not supported by the specification

a. The specification explicitly includes pHs in the scope of "about" that the Exela defendants' proposed construction excludes

The specification repeatedly refers to the pH of the formulation in approximate terms, thus confirming the ordinary meaning of the term. For example, the specification explains that the aqueous liquid carrier has a pH of "about 6 to about 9 or about 10, more preferably about 6 to about 8, and still more preferably about 7.5." [*See* Tab 5 at A0052, '834 patent, Col. 11:3-6] And Example 2 of the '834 patent studied five samples, where "each sample (1 through 5) was subjected to ***a range of pH's from about 7 to about 10*** . . . Conventional HPLC and detection techniques were used to detect and determine the concentrations of soluble brimonidine tartrate. [see] ***Table IV***" [*Id*. at A0054, col. 15:23-33 (emphasis added)] Table IV reports that that "range of pH's from about 7 to about 10" was actually ***6.67 to 10.11***. [*Id*. at A0054, Col. 15, Table IV]

The specification thus explicitly states that about 7 includes 6.67. With this in mind, the Exela defendants' argument that "[a]t no point in the specification does Allergan indicate that the claimed composition can exist at an acidic pH level, e.g., with a pH of less than 7.0" is simply not credible. [D.I. 48, Exela Defs. Br. at 15] Moreover, the three instances in the specification that the Exela defendants rely on to support their contention are of little relevance to this dispute. [*Id*. at 16]. The first two bullets address solubility, and the preference that ***certain*** embodiments are ***more soluble*** in an alkaline environment. *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1377 (Fed. Cir. 2005) (noting "we do not import limitations from a preferred embodiment .

. . .") The patents addressing solubility are not being asserted against the Exela defendants. The last bullet point addresses the pKa of the active ingredient, in this case brimonidine tartrate, and states that its pKa is preferably great than neutral – this has little to do with the pH of the actual composition and is of no assistance in construing "a pH of about 7.0".

The general scope for the term "about" as proposed by Allegan (and Apotex) is also consistent with other examples in the specification. In Example 1, a pH-solubility profile was prepared for a brimonidine tartrate solution. Eight samples were prepared in a "pH range of about 5 to about 8 at 23° C." [*See* Tab 5 at A0053, '834 patent, col. 13:16-20] Table II lists the actual pH's for those eight samples and they range from 5.50 to 7.88. [*Id*. at col. 14, Table II] In other words, "about 5" meant 5.50 and "about 8" meant 7.88. While the Exela defendants place no numerical value on "measurement tolerances," presumably 0.5 pH units would be outside of that range, further demonstrating that the specification did not contemplate that "about" referred merely to tolerances in the pH measurement, as the Exela defendants suggest.

The Exela defendants reference none of these uses of "about" in their brief. Instead, they argue that because the pH is expressed to the tenth of unit in the claims and not whole pH units (7.0 rather than 7), and because the pH scale is logarithmic, one of skill in the art would "immediately recognize the importance of maintaining a pH … as close to a neutral pH of 7.0 (or greater than 7.0) as possible." [D.I. 48, Exela Defs. Br. at 14-15.] The Exela defendants fail to acknowledge that it is clear, even from the limited citations to the specification in its brief, that the inventors used pHs with no tenth of a unit and pHs with a tenth of a unit simultaneously. [Exela Defs. Br. at 16, citing '834 patent 5:65-67] Beyond this, the Exela defendants offer ***nothing*** to support this assertion other than bare argument – and to the extent that "close" does not encompass 6.67, the argument is directly refuted by the specification, as demonstrated above.

4. The caselaw relied on by the Exela defendants' does not support their construction

The Exela defendants rely on three primary cases as alleged support for their construction of "about": *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211 (Fed. Cir. 1995), *Hybritech Inc. v. Abbott Labs*, 849 F.2d 1446 (Fed. Cir. 1988), and *BJ Servs. Co. v. Halliburton Energy Servs.*, 338 F.3d 1368 (Fed. Cir. 2003). The Exela defendants are wrong – none of these cases provide any support for their proposed construction.

In *Pall Corp*, the Court was presented with the construction for the term "about" in reference to a ratio of methylene to amide groups. In reviewing the district court's construction, the Federal Circuit noted that:

> The use of the word "about" avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technological and stylistic context. We thus consider how the term "about 5:1 to about 7:1" was used in the patent specification, the prosecution history, and the other claims.

Pall, 66 F.3d at 1217.

Under this standard, the Exela defendants' arguments fail completely. As for the claims, the Exela defendants point to nothing in the claims of the '834 patent that support their proposed construction, and instead offer different constructions for the multiple uses of the same term in the same claim. As for the specification, the specification says nothing about measurement tolerances. Instead, as demonstrated above, the specification uses the term "about," as it relates to pH, broadly. And the file history also does not detract from the ordinary meaning, as demonstrated in Section 5 below.

The Exela defendants also cite *Hybritech* as supposedly supporting their position. [D.I. 48, Exela Defs. Brief at 13] But *Hybritech* is of little use to this case. Because *Hybritech* was decided long before *Markman*, there was no analysis of the claims, nor any review of the other intrinsic or extrinsic evidence as to the scope of the claim term "about." Rather, in the context of

reviewing a preliminary injunction, the Court found that there was an industry standard with an associated error for performing the measurement at issue. The Court then applied that error in reviewing the test results for that case. *Hybritech*, 849 F.2d at 1453.

As for *BJ Services*, the Exela defendants cite that case for the proposition that "experimental error" is an appropriate way to construe the term "about." [D.I. 48, Exela Defs. Brief at 13] In *BJ Services*, however, it was the patentee that sought a narrow construction of the term "about" to avoid the prior art and preserve the validity of its claims. *BJ Servs.*, 338 F.3d at 1372-73. No such considerations are at issue in this case.

Moreover, the Federal Circuit did not comment on the ordinary meaning of the term in *BJ Services* because neither party had proposed it. Here, of course, two parties are proposing the ordinary meaning, while the other party, on the one hand, seeks to limit the term based on a phrase "within measurement tolerances" that appears nowhere in the patent, while simultaneously applying the ordinary meaning of the term elsewhere *in the same claim*. That same party also fails to explain why the one term "about 7.0" should be "within measurement tolerance," but the other terms "about 21 degrees Centigrade" and "about 0.15% (w/v) [brimonidine]" should not. And that same party makes no account for all the other uses of "about" with pH throughout the specification that refute the proposed construction. The ordinary meaning of the term "about" should control.

5. There was no clear and unmistakable prosecution disclaimer in the prosecution history

The Exela defendants' prosecution disclaimer argument that the limitation requiring a pH of "about 7.0 or greater" cannot cover any formulation having a pH 6.6 to 6.8 or below is also unsupported under the law.

In order for statements made during prosecution to be found to disclaim subject matter encompassed by the literal scope of the claims, the alleged disavowing statements must be "both clear and unmistakable." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003); *see also Cordis Corp. v. Medtronic AVE, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008) (stating that disavowals of claim scope during prosecution will be found only if they constitute "clear and unmistakable surrenders of subject matter").

As alleged support for their disclaimer argument, the Exela defendants rely on a single, cropped statement from the prosecution history, and fail to present that statement within its proper context. Examining the entirety of the prosecution history and the arguments that Allergan made to overcome prior art, however, what becomes clear is that Allergan did ***not*** clearly and unmistakably disclaim formulations in the pH range of 6.6 to 6.8.

During prosecution, the examiner rejected the claims as obvious over the prior art Burke and Beck patents, which do not teach formulating at any specific pH values. [Tab 6 at A0135-41.] In their response, the applicants made minor amendments to the claims that did not concern the pH limitation and argued that the claims were valid because, among other reasons, the invention produced unexpected results in comparison to the prior art ALPHAGAN® 0.2% formulation, which had an off-the shelf pH of 6.3 to 6.5, and a labeled pH range of 5.6 to 6.6. [*Id.* at A0148-52.] The entire section of the response relied on by the Exela defendants reads as follows:

> To appreciate the surprising aspects of the present invention it is important to understand that previous brimonidine solutions for ophthalmic use have been formulated at a pH of about 6.3 – 6.5 and a concentration of 0.2% (w/v). This formulation was approved for marketing in the United States and foreign countries under the trade name Alphagan®.
>
> The present invention is the result of the surprising finding that increasing the pH of a brimonidine solution to a pH of greater than about 7.0 leads to similar efficacy at a 25% lower concentration (from about 0.2% (w/v) to about 0.15%

> (w/v) or less) than is seen in a brimonidine solution at a pH of about 6.6-6.8. This appears to be due to the fact that at a pH closer to the pKa of brimonidine (which has a pKa of about 7.4) than pH 6.3-6.5, a larger proportion of the molecules are electrostatically neutral, and thus less lipophobic than the polarized molecule. …

[*Id.* at A0151 (emphases added).]

The response also discussed the Katz article, stating as follows: "For the Examiner's convenience, Applicants hereby attach a copy of an article, Katz et al., J. Glaucoma 11:119 (April 2002) which shows the comparison of the 0.2% brimonidine formulation having a pH 6.3-6.5 (the '0.2% formulation') with 0.15% brimonidine solution pH 7.2 (the 0.15% formulation)." [*Id.* at A0151.] The declaration attaching the article also noted that the pH of the 0.2% formulation in the article was 6.3 to 6.5. [*Id.* at A0155.]

As is readily apparent when the entire passage is considered, in tandem with the Katz article and the declaration, the applicants were discussing the advantages of their invention over ALPHAGAN® 0.2%, and not over any other formulations with different pH values. The "surprising finding" referred to in the section of the response quoted by the Exela defendants is that increasing the pH of a brimonidine solution to a pH of greater than "about 7.0," as recited in the claims, leads to similar efficacy at a 25% lower concentration than is seen ALPHAGAN® 0.2%, with a pH of ***6.3 to 6.5***. This finding is supported by the study cited in the response and attached to the declaration, which actually tested formulations according to the claimed invention against ALPHAGAN® 0.2%. [Tab 6 at A0156-63.]

Moreover, as the Exela defendants are well aware, there is no prior art of record that shows a pH of 6.6 to 6.8, so it makes no sense that the applicants would have distinguished their claims over a non-existent formulation. To be a disclaimer of claim scope, the patentee must have clearly and unmistakably said what his claim excludes by "explicitly characteriz[ing] an aspect of his invention in a specific manner to overcome prior art." *Purdue Pharma L.P. v. Endo*

Pharms., Inc., 438 F.3d 1123, 1136-37 (Fed. Cir. 2006). The applicants simply did not clearly and unmistakably characterize their invention in manner that would preclude the claims from covering pH values of 6.6 to 6.8.

At most, the applicants' statement regarding "a brimonidine solution at a pH of about 6.6-6.8" is ambiguous. And the Federal Circuit has stated repeatedly that ambiguous statements made during prosecution are not sufficient to find any disclaimer of claim scope. *See, e.g.*, *SanDisk Corp. v. Memorex Prods, Inc.*, 415 F.3d 1278, 1287 (Fed. Cir. 2005) ("There is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term."); *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1332 (Fed. Cir. 2004) (finding no disclaimer because "the statements in the prosecution history are subject to multiple reasonable interpretations, they do not constitute a clear and unmistakable departure from the ordinary meaning of the term [at issue]"); *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1359 (Fed. Cir. 2003) (concluding that a statement made during prosecution "is amenable to multiple reasonable interpretations and it therefore does not constitute a clear and unmistakable surrender").

Indeed, read in the context of the entire file history, rather than in the isolated snippet cited by the Exela defendants, the reference to pH values of 6.6 to 6.8 most likely appears to have been an error and thus not a disclaimer of claim scope. *Cf. IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1433-34 (Fed. Cir. 2000) (concluding that file history statement distinguishing use of M and G codes did not disclaim those codes, when statement was "taken in context, as well as other statements made during prosecution and reexamination"). The

applicants were plainly distinguishing over a formulation at pH 6.3 to 6.5, not a formulation at pH 6.6 to 6.8, and merely erroneously referred to the 6.6 to 6.8 range.

The facts here are similar to those in *Biotec Biologische Naturverpackungen GmbH v. Biocorp, Inc.*, 249 F.3d 1341 (Fed. Cir. 2001), in which the patentee made an argument during prosecution erroneously stating that its process started with water-free starch, even though the specification and claims discussed both water-free and native starch. The patentee argued that it was an "obvious error," and the Federal Circuit agreed, explaining as follows:

> An error in the prosecution record must be viewed as are errors in documents in general: that is, would it have been apparent to the interested reader that an error was made, such that it would be unfair to enforce the error. The defendants do not argue that this statement led them to believe that it clearly limited the invention that was claimed. A person of reasonable intelligence would not be misled into relying on the erroneous statement, for it is contrary not only to the plain language of the claims and the specification, but also to other statements in the same prosecution document.

Id. at 1348. The reference to pH 6.6 to 6.8 in the prosecution history is similarly an obvious error that is contrary to other statements in the rest of the same office action response, and thus cannot be read as disclaiming pH values of 6.6 to 6.8 from the scope of the claims.

6. If any numerical limitation is necessary, "about 7.0" should be construed to be greater than a pH of 6.6

As demonstrated above, the specification explicitly discloses that "about 7.0" includes a pH of 6.67. This general scope of the range for the term "about" is consistent with other examples of the use of "about" in the specification, e.g. "about 5.0" meaning 5.50.[3] The Exela defendants' proposed construction thus attempts to read out of the claims that which the specification makes clear that the claims were intended to cover.

[3] Such a range would also be consistent with the products that these patents cover, and the prior art product, ALPHAGAN® 0.2%, that the applicants distinguished in the file history. ALPHAGAN®, the prior art product, had a labeled pH of 5.6 to 6.6, while ALPHAGAN® P 0.15%, the product that uses the inventions claimed in the patents-in-suit and the product that the Exela defendants are attempting to genericize, has a labeled pH of 6.6 to 7.4.

Accordingly, while Allergan believes it is clear that "about" needs no more construction than the ordinary meaning, should the Court determine that a numerical pH limitation is necessary, the term should be construed such that it includes the examples in the specification, and so that it is consistent with the file history distinguishing pHs 6.5 and below. This would mean that "greater than about 7.0" would cover pHs "greater than 6.6."

B. "Therapeutically effective" should be construed according to its plain and ordinary meaning

The "ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. This is the case here.

As courts have acknowledged, "therapeutically effective" is an easily understood, straightforward phrase:

> The terms 'therapeutically effective' or 'therapeutically ineffective' are commonplace-a juror can easily use these terms in her infringement fact-finding without further direction from the court.
>
> These terms do not need to be construed because they are neither unfamiliar to the jury, confusing to the jury, nor affected by the specification or prosecution history. First, the terms will not be unfamiliar to the jury since "therapeutic," "effective," and "ineffective" are all familiar words. . . . Second, these terms are not confusing. Conducting this inquiry from the perspective of a person of ordinary skill in the art, the court is convinced that the meanings of these words would be clear to her. Third, there is no evidence that the specification or the prosecution history intended a different meaning be attached to these terms. In sum, the court is not persuaded that the terms are ambiguous.

Board of Trustees of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 528 F. Supp. 2d. 967, 976 (N.D. Cal. 2007) (citations omitted).

In their brief, the Exela defendants claim that the ordinary meaning of the term should control. However, rather than simply reading the phrase as written, as urged by Allergan and

Apotex, the Exela defendants proffer a proposed construction that completely rewrites the opening paragraphs of the claim.

1. A therapeutically effective aqueous ophthalmic composition comprising: up to about 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate,	A water-based formulation containing between 0% and about 0.15% (w/v) of brimonidine tartrate for ophthalmic administration that is demonstrated to provide a therapeutic benefit to a patient to whom the formulation is administered.

The Exela defendants do not argue, nor even suggest, that the claim is ambiguous or in any need of clarification. Yet despite that, the Exela defendants attempt to read in limitations that simply are not present in the claim itself. To the extent those limitations come from the specification, and the Exela defendants' brief is not clear on that point, this, too, violates a basic claim construction rule. *See Phillips*, 415 F.3d at 1320; *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) (stating that it is a "cardinal sin" to read a limitation from the written description into the claims.). The rule against importing limitations into claims is succinctly explained as follows: "[i]f everything in the specification were required to be read into the claims, or if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985).

The Exela defendants' additional verbiage is extraneous, unnecessary, and unsupported, and they have offered no support for why their proposed language is more appropriate than that proposed by Allergan and Apotex.[4] The correct construction is to construe the claim in accordance with its plain and ordinary meaning as is appropriate under the case law.

[4] The other two terms "defined" by the Exela defendants – "up to" and "aqueous" – are easily understood terms. There is no need to rewrite them. This is *not* a jury trial. The Court is well aware of the meaning of "aqueous" and "up to."

III. CONCLUSION

Because of the foregoing, the Court should adopt the constructions proposed by Allergan and Apotex.

Dated: June 16, 2008

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